

REMARKS

Applicants thank the Examiner for the thorough examination given the present application.

Status of the Claims

Claims 1-3, 8-11, 13-14, and 16-24 will be pending in the above-identified application upon entry of the present amendment. Claims 1 and 8 have been amended. Claim 7 has been cancelled herein. Support for the recitations in claim 1 can be found in claim 7 as well as in the present specification, *inter alia*, at page 4, line 27 to page 5, line 1 (or paragraph [0020] of U.S. 2005/0234558). Thus, no new matter has been added.

Applicants submit that the present Amendment is merely formal in nature, reduces the number of issues under consideration, and places the case in condition for allowance. Alternatively, entry of the present amendment is proper to place the claims in better form for appeal.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 102(b)

Claims 1-3, 7-8, 11, 13, 14, and 17-24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Leitao (U.S. Patent No. 6,069,295; hereinafter "Leitao '295") (see paragraph 2 of the outstanding Office Action). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested.

Legal Standard for Determining Anticipation

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.” *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001). “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Distinctions over the Cited Reference

With respect to independent claim 1 and those claims dependent thereon, the method of claim 1 comprises “providing a microroughness...by treating the metallic implant surface with an aqueous solution of hydrofluoric acid, wherein the concentration of the hydrofluoric acid is less than 0.5 M, **resulting in etching, for an etching period of up to 180 seconds at room temperature**; wherein said microroughness comprises pores and peaks having a pore diameter of $\leq 1 \mu\text{m}$, a pore depth of $\leq 500 \text{ nm}$, and a peak width, at half the pore depth, of from 15 to 150% of the pore diameter” (emphasis added).

In stark contrast, Leitao '295 relates to a process comprising subjecting a non-porous material to a mechanical or chemical surface treatment until a surface roughness with an average peak distance (Ra value) between 10 and 1,000 nm is obtained.

Several mechanical and chemical surface treatments are exemplified in Leitao '295, and treatment with a strong, preferably mineral, acid solution *such as hydrofluoric acid* is merely one example of such suitable treatment (col. 2, lines 42-55). However, no further details on the HF treatment are provided in Leitao '295. The only disclosure given in relation to the methods of treatment is that "it is important that the surface roughness is performed under controlled conditions to ensure uniform result" (col. 2, lines 55-57). No information is given as to the meaning of such "controlled conditions."

In particular, in the present invention, in order to obtain a surface roughness comprising pores and peaks having a diameter of $\leq 1 \mu\text{m}$, a pore depth of $\leq 500 \text{ nm}$, and a peak width, at half the pore depth, of from 15 to 150% of the pore diameter, which has been shown to give surprisingly good biocompatibility results (see paragraph [0021] of the present published application), the concentration of the hydrofluoric acid should be less than 0.5 M, the treatment should result in an etching process, and the etching period should be up to 180 seconds at room temperature. The concentration of HF (aq) determines the ratio between etched areas; i.e., areas having a microroughness, and non-etched areas (paragraph [0063]). Regarding the surprising results, the present invention achieves both an improved rate of attachment and a stronger bond between the implant surface and bone tissue. Leitao '295 gives no guidance or disclosure to one of ordinary skill in the art on how to achieve the instantly claimed hydrofluoric acid concentration as well as the advantages of the present invention.

In other words, Leitao '295 fails to disclose any details of a method wherein a surface roughness may be obtained as achieved by the present invention by varying the concentration, treatment time, etc. Accordingly, Leitao '295 fails to disclose all claimed features of instantly pending claim 1, and those claims dependent thereon.

As such, the present invention is not anticipated by Leitao '295 since the reference does not teach or provide for each of the limitations recited in the pending claims.

For completeness, Applicants also respectfully submit that Leitao '295 does not render the present invention obvious because neither the reference nor the knowledge in the art provides any disclosure, reason, or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed.

With respect to independent claim 13 and those claims dependent thereon, the implant surface according to the present invention comprises a microroughness with the following features:

i) A *pore diameter* of $\leq 1 \mu\text{m}$ defined as the distance between the highest points of two adjacent peaks (D_1 and D_2 in Fig. 1 below);

ii) A *pore depth* of $\leq 500 \text{ nm}$ defined as the distance between an imaginary line drawn between the highest points of two adjacent peaks and the bottom of the pore (h_1 and h_2 in Fig. 1);

iii) A *peak width, at half the pore depth*, of from 15 to 150% of the pore diameter (x_1 and x_2 in Fig. 1); and

iv) a *root-mean-square roughness* (R_q and/or S_q) of $\leq 250 \text{ nm}$.

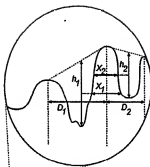


Fig 1

In contrast, Leitao '295 specifies a microroughness with an average peak distance (defined as the average spacing between protrusions on the surface) between 10 and 1,000 nm and a pore depth (defined as the peak height with respect to the deepest sites on the surface) of at least 20 nm up to about 2,000 nm. Leitao '295 discloses that the surface roughness is a critical factor (col. 1, line 43). However, the advantageous effects associated with the article of Leitao '295 appear to be linked to the provision of a layer of calcium phosphate as shown in the examples of Leitao '295. Furthermore, the pore depth is said to be less critical than the peak distance (col. 1, lines 58-59).

One of ordinary skill in the art would know that the morphology of the implant surface has an impact on the rate of osseointegration. An increased surface roughness gives a larger contact and attachment area between the implant and the bone tissue so that a better mechanical retention and strength may be obtained (paragraph [0011] of the published application).

However, the specific micro or macroroughness provided on an implant surface may give rise to variations with respect to the osseointegration process and the rate of attachment to bone tissue. The present invention provides surprisingly good biocompatibility results for an implant having the microroughness as claimed in claim 13. Both an improved rate of attachment and a

stronger bond between the implant surface and the bone tissue are obtained. The fine microroughness improves the osseointegration process (paragraph [0021] of the published application).

The microroughness defined in claim 13 differs from the roughness disclosed in Leitao '295, and the roughness parameters (i.e., pore diameter and peak width) do not correspond to the definitions provided in Leitao '295. Both the pore diameter and the pore depth are more specifically described in the present application, and the combination of the specific pore diameter and pore depth as defined in claim 13 achieves the beneficial effects of the present invention. In contrast, Leitao '295 discloses that the pore depth is less critical (col. 1, lines 58-59).

Furthermore, the peak width, at half the pore depth, of the article of Leitao '295 cannot be assumed to be within the range of 15 to 150% since Leitao '295 remains silent on any details on this roughness.

For the reasons given above, Leitao '295 fails to disclose all claimed features of instantly pending claim 13, and those claims dependent thereon. As such, the present invention is not anticipated by Leitao '295 since the reference does not teach or provide for each of the limitations recited in the pending claims.

For completeness, Applicants also respectfully submit that Leitao '295 does not render the present invention obvious because neither the reference nor the knowledge in the art provides any disclosure, reason, or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed.

Issues under 35 U.S.C. § 103(a)

Claims 9-10 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leitao '295 in view of Hama et al. (U.S. Patent No. 4,818,559; hereinafter "Hama et al. '559") (see paragraph 3 of the outstanding Office Action). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Exemplary rationales that may support a conclusion of obviousness include:

- (a) combining prior art elements according to known methods to yield predictable results;

- (b) simple substitution of one known element for another to obtain predictable results;
- (c) use of known technique to improve similar devices (methods, or products) in the same way;
- (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) “obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

Distinctions over the Cited References

As discussed above, Leitao ‘295 does not disclose each and every aspect of claims 1 and 13, from which claims 9-10 and 16 ultimately depend. For instance, Leitao ‘295 fails to disclose any details of a method wherein a surface roughness may be obtained as achieved by the present invention by varying the concentration, treatment time, etc. Applicants respectfully submit that Hama et al. ‘559 do not overcome the deficiencies of this reference.

The etching conditions are important in achieving the desired microroughness, i.e., a microroughness comprising pores and peaks having a pore diameter of $\leq 1 \mu\text{m}$, a pore depth of $\leq 500 \text{ nm}$, and a peak width, at half the pore depth, of from 15 to 150% of the pore diameter.

Etching with hydrofluoric acid at different concentrations may result in very different roughness morphologies on an implant surface. In fact, Hama et al. '559 describe that its treatment with hydrofluoric acid results in large surface irregularities in the range of 15 μm to 100 μm (col. 3, lines 30-32). Referring to, e.g., WO 95/17217, which is mentioned in the background description of the present application, treatment with hydrofluoric acid results in an implant surface which is unaffected and wherein no significant etching occurs. The combination of Leitao '295 and Hama et al. '559 fails to provide any guidance in achieving the microroughness of the present invention to one of ordinary skill in the art. Accordingly, Applicants respectfully submit that the cited combination of Leitao '295 and Hama et al. '559 is improper.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Leitao '295 in view of Hama et al. '559 fail to disclose all of the claim limitations of independent claims 1 and 13, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious. Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

CONCLUSION

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case clearly indicating that each of claims 1-3, 8-11, 13-14, and 16-24 are allowed and patentable under the provisions of title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Reg. No. 58,258 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: April 16, 2009

Respectfully submitted,

By 

Craig A. McRobbie

Registration No.: 42,874

for BIRCH, STEWART, KOLASCH & BIRCH, LLP *#43,368*

8110 Gatehouse Road, Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicants